

§ 72.148

control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee and certificate holder shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee and certificate holder shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

§ 72.148 Procurement document control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, or by their contractors and subcontractors. To the extent necessary, the licensee, applicant for a license, certificate holder, and applicant for a CoC, shall require contractors or subcontractors to pro-

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vide a quality assurance program consistent with the applicable provisions of this subpart.

§ 72.150 Instructions, procedures, and drawings.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 72.152 Document control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.

§ 72.154 Control of purchased material, equipment, and services.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall have available documentary evidence that material and